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Sent: Thursday, February 07, 2013 1:42 PM
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Cc: Elian, Albert (POL); Juhascik, Matthew (POL); Morrison, Cathleen (POL); Sullivan, Kristen (POL)
Subject: Clarification on some QA points,

We have received clarification on some major points from QA. Please review the following information. Changes will be made to update existing protocols as applicable. If you have any questions, please see me.

Thank you.
Nancy

- 1) Inclusion of all case information/data in case file, i.e. what to do with data that is not used?

We should be retaining all case information within the case file.

If contamination and/or carryover occur, then new samples should be pulled to run (i.e. fresh aliquots from test tubes, no repeated injection of the same autosampler vial).

Any data that is not presented on a report needs to have documentation on the data explaining why it wasn't included.

NOTE: There will be an Excel spreadsheet to record any contamination/carryover occurrences in both Drugs and Tox. This is in the process of being established.

- 2) Lab numbers and initials on all pages of the police report

CMU will be responsible for re-stapling the packets together after they have fulfilled the discovery requests. We can continue to initial and date the front of police report.

- 3) Note to file in "supplements" records of edit within LIMS

ANY and ALL changes in LIMS should have a "note to file". This also pertains to corrected and supplemental reports, and "kicking back" of reports after batch approval - documentation of changes needed or made should be reflected in the NTF.

- 4) Reference standard verification: i.e. straight from the vial – take an aliquot and then dilute

From this point on – run your diluted/prepared solution/control s in addition to the solvent used for preparation as part of your verification process.

NOTE: This applies to casework as well - run a solvent control with all prepared samples using the same solvent used to prepare samples (this will be treated similar to a "case sample" and is not be confused with the solvent blank that is routinely maintained on the instruments).

Verification of all prepared solutions must be done prior to their use in case work.

5) Do not re-use any "consumables"

i.e., pipette tips- do not leave or re-use pipette tips on single-use pipettes

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